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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,548	10/22/1999	DAVID ROBBINS	DEX-0054	2041

7590 03/23/2004

JANE MASSEY LICATA
66 E MAIN STREET
MARLTON, NJ 08053

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/426,548

Applicant(s)

ROBBINS ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 29, 2003 has been entered.

DETAILED ACTION

This application claims benefit to provisional application 60/105,180, filed October 22, 1998.

Applicants amendment filed December 29, 2003, has been received and entered. Claim 9 has been amended. Claims 2, 3 and 9 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 9 recites the limitation "in the sample" in the final line. There is insufficient antecedent basis for this limitation in the claim. The claim provides for a DNA or RNA sample to which the probes are capable of binding, but not to a sample in general. It is

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unclear if the binding is made to a specific DNA or RNA and/or in what context. Further, the metes and bounds of the claim are unclear because the conditions under which the claimed probes are "capable of binding" are not clearly set forth. Binding conditions are subject to variation, and therefore, the metes and bounds of the claim would be subject to this variation. Further, the specification provides several methods in which probes are used, each requiring different buffers and binding conditions. In view of the various methods using the binding of probes and any of the particular conditions associated with such a probes the claim indefinite because they would be subject to how the probe was used. For example, in one case a particular probe may meet the limitations of the claims because of its use in a specific method, yet in another method would not meet the limitations of the claims.

As indicated in the previous office action ,claims 2 and 3 are not included in the basis of the rejection because they more clearly set forth that binding of the probe is indicative of the presence of the specific hMLH1 and hMSH2 mutations. In this case, the functional limitations for practicing the claimed method are clearly set forth as a definable property of binding of the probes set forth in claim 9.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Weber *et al.*

Claim 9 stand rejected under 35 U.S.C. 102(e) as being anticipated by Liskay *et al.*

Applicants note the amendments to claim 9, and argue that the amendment is similar to that provided in claims 2 and 3 after which the rejection was withdrawn. See Applicants' amendment, pages 7-8, Section II. Applicants' arguments have been fully considered, but not found persuasive.

The amendment to the claims to indicate that the probe used in the screening is directed to hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3 and that binding of the probe to the sample indicates the presences of hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3, is noted. The specification provides various types of methods and probes to detect altered sequences. In particular, the specification provides a method termed ligase chain reaction (LCR)(page 18, lines 14-26). In the method, various complimentary primers are used including ones that are complimentary to normal sequence. By using varying hybridization conditions, one can obtain reduced hybridization which would be indicative of a mismatch. Therefore, given this guidance the sequences taught by Weber *et al.* and Liskay *et al.* will anticipate the product of claim 9. Unlike the methods set forth in claims 2 and 3 which require binding as an indication of the presence of a given mutant, the product of claim 9 has no such requirement, only requiring that it bind any of the given mutants set forth in the claims.

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Because the normal sequence can bind these sequences and the specification and art provides methods for using these sequences in determining the presence or absence of an alteration, the sequences of Weber *et al.* and Liskay *et al.* anticipate the claims.

Conclusion

No claim is allowed.

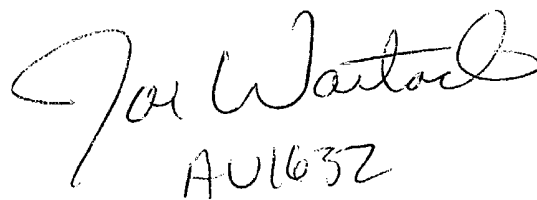
Claims 2 and 3 are objected to for being dependent on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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